UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,800	03/31/2006	Christopher C. Broder	044508-5023	9160

9629 7590 04/28/2008

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,800	BRODER ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,23-26 and 31-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19,23-26 and 31-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *March 23, 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention III in the reply filed on February 1, 2008 is acknowledged.

Claims 16-19, 23-26 and 31-46 are examined on the merits, claims 31-46 are new claims.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 1, 2008 was filed after the mailing date of the restriction requirement on September 20, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/331,231, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. There is no support for SEQ ID NO: 1 or 2 in the '231 provisional, therefore, the priority date to claims 16-19, 23-26 and 31-46 is that of PCT/US02/36283, filed on November 13, 2002, which does support the claimed polypeptide sequences of SEQ ID NO:s 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (PNAS, 1996), Young et al. (Virology, 1997), Bossart et al. (Virology, 2001), Genbank (Accession # AF212302, 2001) and Wang et al. (Journal of Virology, 2000).

The claimed invention is drawn to a method of inhibiting the fusion between the membrane of a paramyxovirus, such as HeV or NiV, and the plasma membrane of a cell by

administering an effective amount of SEQ ID NO: 1 and/or SEQ ID NO: 2 with a pharmaceutically acceptable carrier.

Lambert et al. teach the use of fragments from the fusion proteins of paramyxoviruses, respiratory syncytial virus (RSV), human parainfluenza virus 3 (HPIV-3) and measles virus (MV) in order to inhibit viral fusion of target cells. Through their research, Lambert et al. determine that these fragments are potent antiviral proteins which can be tested for clinical applications. However, Lambert et al. do not teach the use of SEQ ID NO: 1 and/or SEQ ID NO: 2 from HeV or NiV.

Young et al. teach the analysis of peptide based inhibitors of Newcastle Disease virus (NDV, which is a paramyxovirus) fusion with a target cell. Young et al. employ a fragment of the NDV fusion protein of the amino acids-ALDKLEESNSKLDKVNVKLT, which are residues 478-497, in order to inhibit fusion. However, Young et al. do not teach the use of SEQ ID NO: 1 and/or SEQ ID NO: 2 from HeV or NiV.

Bossart et al. teach the use of a derivative of SEQ ID NO: 1 in inhibiting the fusion of a recombinant vaccinia virus expressing HeV G and F glycoproteins with target cells. Bossart et al. also disclose a 47 amino acid sequence in figure 4b that contains SEQ ID NO: 1 from residues 6-47. However, Bossart et al. do not use the entire sequence of SEQ ID NO: 1 and do not teach the use of SEQ ID NO: 2. In fact, the derivative of SEQ ID NO: 1 is (HQSIQT*KVDISSQISSMNQSLQQSKDYIKEAQKILDTVNPSL*) with the italics representing residues 7-42 of SEQ ID NO: 1.

The Genbank Accession of the complete genome of Nipah virus is represented by accession # AF212302, published in 2001. The Fusion protein is located from bases 6370-8706, which contains SEQ ID NO: 2 from residues 447-488.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Lambert et al. and Young et al. in order to inhibit HeV or NiV fusion with a target cell by administering SEQ ID NO:1 and/or SEQ ID NO: 2. One would have been motivated to do so, given the suggestion by Lambert et al. and Young et al. that the method be used to inhibit paramyxovirus fusion. There would have been a reasonable expectation of success, given the knowledge that a sequence containing SEQ ID NO: 1 was disclosed prior to the instant invention and that a derivative of SEQ ID NO: 1 was used in inhibiting HeV F protein fusion with a target cell, as taught by Bossart et al., and also given the knowledge that the sequence was also known for SEQ ID NO: 2 prior to the instant invention, as taught by Genbank Accession # AF212302. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-26 and 31-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting viral infection in Vero Cells *in vitro*, does not reasonably provide enablement for preventing paramyxovirus viral infection by administering SEQ ID NO:1 and/or SEQ ID NO: 2 or treating any viral infection with SEQ ID NO: 1 and/or

SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Nature of the invention/Breadth of the claims. The claimed invention is drawn to a method of either treating a viral infection with SEQ ID NO: 1 and/or SEQ ID NO: 2 or preventing a paramyxovirus infection in a subject (such as a human) by administering a polypeptide comprising or consisting of SEQ ID NO: 1 and/or SEQ ID NO: 2 as a vaccine. The paramyxovirus can be either the Hendra or Nipah virus.

State of the prior art/Predictability of the art. The art does not recognize any vaccine that can either treat or prevent Hendra or Nipah viral infections or infections of paramyxoviruses in subjects such as humans. Holbrook et al. (Antiviral Research, 2008) teach that for viruses from the families of *Flaviviridae*, *Togaviridae* and *Paramyxoviridae* (even for viruses of the genus *Henipavirus*), no vaccines are available. Moreover, Patch et al. (Virology Journal, 2007) state that no therapeutics involved in treating or preventing infections by Hendra virus or Nipah virus exists. Lastly, Mungall et al. (Journal of Virology, 2006-authored with Co-inventors Bossart and Broder) state that their Nipah virus subunit vaccine, while inducing immune responses in cats and providing limited protection, does provide a vaccine or the prevention of infection.

Working examples. The only working examples provided related to testing various peptide concentrations of SEQ ID NO: 1 or 2 and the resulting inhibition of Hendra or Nipah viral infection on Vero cells *in vitro*. However, even at a high peptide concentration of 112 uM viral infection was not completely inhibited. In addition, no working examples detailing the

polypeptides of SEQ ID NO:1 or 2 and the inhibition of paramyxovirus infections other then HeV or NiV were tested or the analysis of treating or preventing a viral infection *in vivo* with these polypeptides.

Guidance in the specification. The specification states that by administering the polypeptides of SEQ ID NO:s 1 and/or 2 to a host, viral infections, such as paramyxovirus infections, can be treated and/or prevented.

Amount of experimentation necessary. Additional research is required in order to determine how effective a subunit vaccine or any vaccine for that matter at treating and/or preventing paramyxovirus infections, particularly those resulting from either Hendra or Nipah virus given the state of the art (i.e., unpredictable nature) or the lack of working examples in the specification.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how one can treat an infection with a virus since the virus would cause an infection when administered, as recited in claim 23, "A method for treating infection with a virus…". Perhaps amending claim 23 to recite, "A method for treating

an infection by a virus…" or "A method for treating a viral infection…". Claims 24-26 are also rejected since they depend from claim 23.

Claim 44 recites, "The method of claim 31, wherein the polypeptide is a fusion protein.", however it is unclear if this limitation is further describing the polypeptides of SEQ ID NO:s 1 and 2 of claim 31, since these are Hendra virus and Nipah virus Fusion (F) glycoproteins, respectively, or if this new limitation implies that the polypeptide is in fact a fusion protein (i.e., linking of two heterologous proteins to form a hybrid/fusion protein).

Claim Objections

Claims 18 and 41 are objected to because of the following informalities: *Paramyxovirina* is misspelled. Please replace with *Paramyxovirinae*. Appropriate correction is required.

Claims 19, 26 and 42 are objected to because of the following informalities: since the abbreviations, HeV and NiV (which are both recited in claims 19, 26 and 42) are not well known in the art (as compared to DNA or RNA, for example), please amend the claims to recite, "…Hendra virus (HeV) or Nipah virus (NiV)." Appropriate correction is required.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648